MASSACHUSETTS COVID-19 VACCINE PROGRAM

COVID-19 Vaccine Guidance for Vaccine Providers

Updated March 18, 2021

This guidance provides information on:

- Becoming a COVID-19 vaccine provider
- Information about COVID-19 vaccine products
- Requesting vaccine and reporting to the Massachusetts Immunization Information System (MIIS)
- Storage and handling
- Clinical considerations

This guidance is current as of the date above. Carefully review the weekly Massachusetts COVID-19 Program (MCVP) Bulletin for the most up-to-date information on priority groups currently eligible for COVID-19 vaccination, vaccine supply, process for requesting vaccine, and updated clinical considerations regarding COVID-19 vaccination. The weekly Bulletin is emailed to the vaccine coordinators identified on the MCVP Provider Agreement, and are posted here.

Becoming a COVID-19 vaccine provider

1. Confirm that your facility is fully registered and can submit vaccine-administered data to the Massachusetts Immunization Information (MIIS). Contact the MIIS Unit for more information: miishelpdesk@mass.gov.
2. Request, sign, and electronically submit the MCVP Agreement Form. Contact the DPH Vaccine Unit for more information: dph-vaccine-management@massmail.state.ma.us.
    - **Please note**: Sites or providers that complete the MCVP agreement are not guaranteed to receive COVID-19 vaccine. At this time COVID-19 supplies are extremely limited and vaccine is being prioritized to high throughput sites and newly enrolled sites will not receive vaccine allocations for the foreseeable future.

Importance of trained healthcare professionals

A large number of healthcare professionals are needed to support COVID-19 vaccination efforts nationwide. These healthcare professionals are essential to ensuring the American population is vaccinated safely as soon as possible. They play critical roles in proper vaccine storage, handling, preparation, and administration, and they must be prepared to respond to vaccine recipients' questions and concerns. It is important these healthcare professionals receive the training needed to effectively meet the demands of their roles. Training must be ongoing as new COVID-19 vaccines become available and as vaccine recommendations evolve when we learn more about the vaccines and how to improve the vaccination process. CDC COVID-19 Vaccination Training and Education can be found at: https://www.cdc.gov/vaccines/covid-19/training.html

Emergency Use Authorization of COVID-19 vaccines

There are currently three COVID-19 vaccines that have received emergency use authorization (EUA) from the FDA and are recommended by the Advisory Committee on Immunization Practices (ACIP). The

ACIP does not state a product preference; persons may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them.

- The FDA-issued EUA and Fact Sheet for Healthcare Providers Administering Vaccines should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of COVID-19 vaccines.
- EUA fact sheets for vaccine recipients are available for each product in multiple languages. The EUA fact for vaccine recipients must be provided for to each recipient or their caregiver prior to administration of each dose.
- EUA fact sheets for both providers and vaccine recipients can be found at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Summary of information for each COVID-19 vaccine product

	Pfizer	Moderna	Janssen
Age group	≥ 16 y/o	≥ 18 y/o	≥ 18 y/o
Dose schedule	2 doses, 3 weeks apart	2 doses, 4 weeks apart	Single dose
Dose/route	0.3 mL/intramuscular	0.5 mL/ intramuscular	0.5 mL/ intramuscular
Reconstitution	Reconstitute with 1.8 mL of sterile Sodium Chloride Injection, USP. Use within 6 hours of dilution.	No	No
Standing orders	https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/Janssen-Standing-Orders.pdf
Storage/handling summary	https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf	https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-storage-handling-summary.pdf
Expiration date	On vials	Scan the QR code located on the vial or carton or go directly to http://www.modernatx.com/covid19vaccine-eua	Scan QR code on outer carton or call 1-800-565-4008 or go to www.vaxcheck.jnj
Return shipping container information	https://www.cvdvaccine-us.com/images/pdf/Return%20Instructions.pdf	Use the mailing label on the inside of a flap on the box.	Do not return shipping containers.
Website for more information	www.cvdvaccine.com	https://www.modernatx.com/covid19vaccine-eua/providers/	https://www.janssencovid19vaccine.com/

For all COVID-19 vaccines

- Both doses of a 2-dose schedule should be the same COVID-19 vaccine product.
- COVID-19 vaccines should routinely be administered alone, with a minimum interval of 14 days before or after administration with any other vaccine.
- During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
- Do not shake vials of COVID-19 vaccine.
- Use CDC's expiration date tracking tool.
- Ancillary supplies, including syringes, needles, vaccination record cards, and personal protective equipment to support COVID-19 vaccinations, are supplied by the US Government. The ancillary kit is delivered separately from the vaccine. Unpack the kit and check for receipt of the correct administration supplies and quantities. For problems regarding the ancillary kits, contact McKesson Customer Service at 833-272-6634 or email SNSSupport@McKesson.com.

Special considerations for Pfizer COVID-19 vaccine

- Getting 6 doses from Pfizer vials:
  - Use low dead-volume syringes and/or needles to withdraw 6 doses.
  - If sufficient quantities of low dead-volume syringes are not available OR a 1.5-inch needle is needed, withdraw vaccine using a combination of low dead-volume syringes and non-low dead-volume syringes (e.g., 3 low dead-volume syringes and 3 non-low dead-volume syringes) per vial.
  - Slowly inject the diluent to prevent excess foaming or bubbling.
  - When mixing and withdrawing vaccine, insert the needle into different places on the vial septum.
  - Review CDC's new Preparation Infographic poster, which highlights how to withdraw 6 doses of vaccine from a Pfizer vaccine vial.
  - Never mix partial doses from more than one vial to make a full dose.
  - If unable to get 6 full doses from a Pfizer vial, report one dose wasted in the MIIS.

Requesting COVID-19 vaccine

At this time COVID-19 supplies are extremely limited and vaccine is being prioritized to high throughput sites and newly enrolled sites will not receive vaccine allocations for the foreseeable future. For those that are currently receiving weekly vaccine allocations please keep in mind the following information:

- Providers must use vaccine within 10 days of receipt.
- DPH prioritizes allocation of COVID vaccine for 2nd doses.
- Do not hold vaccine for 2nd doses in reserve. Use vaccine in your inventory for both 1st and 2nd doses.
- Vaccine allocations are based on vaccine usage calculated by dividing the cumulative number of doses received by the number of doses administered. For all sites excepted Community Health Centers (CHCs) providers must meet a threshold of 85% to receive additional doses (for CHCs the threshold is 65%).

Reporting to the Massachusetts Immunization Information System (MIIS)

Provider sites must comply with the MIIS Reporting Order for COVID Vaccine to report vaccine administration data to the MIIS within **24 hours**. Doses administered information in the MIIS and the number of doses available to Massachusetts are used to determine your allocations. If report doses administered are not reported to the MIIS, it will appear that the provider has more inventory than they may actually have on hand. **This will reduce their next allocation.**

- Providers must comply with the reporting requirements as outlined in 105 CMR 222.1000(D) including demographic information.
- For providers without the capacity to automatically report doses administered via an electronic health record, the Clinic Roster functionality allows for easy reporting of a single lot number of vaccine that was administered by the same clinician to multiple patients, as in the case of a large vaccine clinic. This MIIS mini-guide describes how to create, search for, and submit a clinic roster to the MIIS.
- Answers to most questions about using the MIIS can be found at www.miisresourcecenter.com

Receipt of vaccine shipments

When a shipment arrives, open vaccine packages **immediately**, check the temperature monitor reading, inspect the vaccine boxes, compare the vaccine received with the vaccine products that show on the packing list, and store at the appropriate temperature. If you believe that a vaccine shipment has been compromised, temperature monitors are out-of-range, or a warm indicator is not activated, **contact the distributor/manufacturer immediately**. Contact information is included in the shipment boxes.

- Inspect ancillary kits for damage and check the package against the packing list. If the product is damaged or does not match the packing list, **contact McKesson immediately.**
- Calls about vaccine viability, damage, or packing slip discrepancies must reach McKesson (for Moderna and Janssen vaccine) or Pfizer (for Pfizer vaccine) the same day the shipment arrived at the office as documented by the carrier.
    - McKesson: 833-343-2703 or COVIDVaccineSupport@McKesson.com
    - Pfizer: 800-666-7248 or cvgovernment@pfizer.com

Storage and handling

- The CDC Vaccine Storage and Handling Toolkit has been updated to reflect specific information for Pfizer and Moderna, including transport information.
- The USP COVID-19 Vaccine Handling Toolkit provides specific information on transporting vials and predrawn syringes.
- Use the COVID-19 Vaccine Management Standard Operating Procedure (SOP) Template to ensure the vaccine cold chain is maintained for optimum potency. All staff handling vaccines must read, sign, and adhere to the protocols described in this document.

Vaccine wastage

Providers should make every effort to reduce lost or expired COVID-19 vaccine. If vaccine is lost/expired, report the wastage in the Vaccines Module of the MIIS. Review the MIIS Storage/Handling

Issue Mini Guide for instructions. Failure to properly report vaccine wastage causes inaccurate inventories leading to less vaccine being allocated to you in future orders.

Vaccine redistribution

It is critical to document all vaccine transfers in the MIIS; failure to do so will cause inaccurate inventories leading to less vaccine being allocated to you in future orders. You should only transfer COVID-19 vaccine to providers that have completed the MCVP agreement. Providers receiving COVID-19 vaccine should confirm what has been physically received is what has been transferred before completing the transfer. Please review:

- Transferring vaccine from one site to another 6-minute video instruction video
- How to Login and Navigate the MIIS
- How to Complete a Transfer Mini Guide
- Quick Start – Complete a Transfer

Transporting COVID-19 vaccines

CDC guidance on transport of mRNA COVID-19 vaccines allows for the transport of punctured vials, as long as the cold chain is maintained. Transporting vaccine in prefilled syringes is discouraged but, when necessary, may be done with strict adherence to the guidance in the USP COVID-19 Vaccine Handling Toolkit.

Clinical considerations for the administration of COVID-19 vaccines

See CDC Interim Clinical Considerations for Use of COVID-19 Vaccines for updated information on:

- Administration of 2nd doses
- Interchangeability of COVID-19 vaccine products
- Vaccination of persons with SARS-CoV-19 infection or exposure
- Vaccination of pregnant people and those with certain medical conditions
- Patient counseling
- Contraindications and Precautions
- Vaccine administration errors and deviation

Contraindications

A history of the following is a **contraindication** to vaccination with COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine.
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.
- For more information on contraindications for COVID-19 vaccines, see CDC Interim Clinical Considerations for Use of COVID-19 Vaccines.

Precautions

A history of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous

immunotherapy for allergies, i.e., "allergy shots"]) is a **precaution** but not a contraindication to vaccination.

- People with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction, have a precaution to vaccination.
- People with a contraindication to one type of the currently authorized COVID-19 vaccines (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector).
- For more information about precautions for COVID-19 vaccines, see CDC Interim Clinical Considerations for Use of COVID-19 Vaccines.

Routine observation periods following COVID-19 vaccination

CDC currently recommends that persons without contraindications to vaccination who receive a COVID-19 vaccine be observed after vaccination for the following time periods:

- 30 minutes:
    - Persons with a history of an immediate allergic reaction of any severity to another (non-COVID-19) vaccine or injectable therapy
    - Persons with a history of anaphylaxis due to any cause
- 15 minutes: All other persons

Note: Persons may be observed for longer, based on clinical concern. For example, if a person develops itching and swelling confined to the injection site during their post-vaccination observation period, this period may be extended to assess for development of any hypersensitivity signs or symptoms consistent with anaphylaxis.

Managing severe allergic reactions following COVID-19 vaccination

Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported following vaccination with COVID-19 vaccines. See CDC: Interim considerations: preparing for the management of anaphylaxis after COVID-19 vaccination.

- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times. Vaccination sites should plan adequate staffing and supplies (including at least 3 doses of epinephrine) for the assessment and management of anaphylaxis.
- See Medical Management of Vaccine Reactions in Adults in a Community Setting, which includes standing orders for management of anaphylactic reactions in adults in a community setting.
- Patients should be screened prior to receipt of each vaccine dose, and persons with a contraindication (including history of a severe or immediate reaction following the first dose of mRNA COVID-19 vaccine) should not be vaccinated. A COVID-19 prevaccination questionnaire is available to assist with screening.

Reporting adverse events and administration errors to the Vaccine Adverse Event Reporting System (VAERS)

Providers must report the following events to VAERS (https://vaers.hhs.gov/)

- Vaccine administration errors whether or not associated with an adverse event. Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in *Appendix A. Vaccine administration errors and deviations*
- Serious adverse events, irrespective of attribution to vaccination, including:
    - Death.
    - A life-threatening adverse event.
    - Inpatient hospitalization or prolongation of existing hospitalization.
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
    - A congenital anomaly or birth defect.
    - An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
    - Cases of Multisystem Inflammatory Syndrome (MIS) in adults.
    - Cases of COVID-19 that result in hospitalization or death.

Adverse events should also be reported to the specific vaccine manufacturer following the instructions in the EUA fact sheets for providers.

V-safe After Vaccination Health Tracker

Providers should give all vaccine recipients information and encourage them to enroll in **v-safe**, a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination. Through **v-safe**, vaccine recipients report side effects to CDC and receive reminders about their second COVID-19 vaccine dose if they need one. For more information and fact sheets for vaccine recipients, go to https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

Where to go when you have questions about COVID-19 vaccines

Save time by contacting the correct source to answer questions and resolve issues. Please check the following contacts when deciding whom to contact for assistance.

Important: Calls about vaccine viability, damage, or packing slip discrepancies must reach McKesson (for Moderna and Janssen vaccine) or Pfizer (for Pfizer vaccine) the same day the shipment arrived at the office as documented by the carrier.

- **Pfizer vaccine shipment has a problem:**
    - Pfizer Customer Service: 800-666-7248, Email: cvgovernment@pfizer.com
- **Moderna or Janssen vaccine shipment has a problem:**
    - Phone: 833 272-6635 Monday-Friday, 8 a.m.- 8 p.m. ET
    - Email (only send after hours): COVIDVaccineSupport@McKesson.com
- **Ancillary kit has a problem:**
    - McKesson Customer Service: 833-272-6634, Email: SNSSupport@McKesson.com
- **For clinical questions regarding COVID-19 vaccine** (https://www.cdc.gov/cdc-info)
    - Call 1-800-232-4636 or email using the CDC-Info web form

- **Vaccine Unit** (dph-vaccine-management@massmail.state.ma.us)
    - Enrollment into MCVP
    - Vaccine storage and handling and transfer
    - Vaccine shipments, inventory, and number of doses allocated
    - Vaccine wastage/expiration
- **MIIS** (miishelpdesk@mass.gov) Due to the volume of inquiries, it is taking 2-3 business days for the Help Desk to respond. Answers to most questions can be found at the MIIS Resource Center.
    - MIIS registration/onboarding
    - How to log in to the MIIS and report vaccines to the MIIS
    - Running reports in the MIIS
    - Adding users/sites to the MIIS
- **COVID-19 email box** (COVID-19-Vaccine-Plan-MA@mass.gov)
    - Who can get vaccine
    - Vaccine prioritization
    - Where and how to get vaccinated